

## **ATTACHMENT 3**

### **STAFF ANALYSIS OF PUBLIC COMMENTS**

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### INTRODUCTION:

NRC staff received two comment letters in response to the notice that the Governor of Wisconsin has proposed to enter into an Agreement with the Commission under Section 274b of the Atomic Energy Act. The notice was published in the Federal Register (FR) on April 8, April 15, April 22, and April 29, 2003. The notice contained a summary of the staff's draft assessment of the proposed Wisconsin program. In the FR notice, comments were requested in two categories: (a) the proposed Agreement; and (b) the NRC staff's assessment of the Wisconsin radiation control program.

### (1) COMMENTS ON THE PROPOSED AGREEMENT

Comments regarding the proposed Agreement have been grouped into three principal areas: (a) Supporting the Agreement; (b) Opposing the Agreement; and (c) Other.

#### **(a) Comments Supporting the Agreement**

**Commenter:**

**Affiliation:**

Ronald Fraass

Executive Director - Conference of Radiation  
Control Program Directors, Inc.

#### Summary of Comments:

A letter received from the Executive Director of the Conference of Radiation Control Program Directors, Inc. (CRCPD) strongly supported the proposed Agreement between the Nuclear Regulatory Commission and the State of Wisconsin. The letter stated that the CRCPD members and staff worked with the State of Wisconsin for several years while they prepared to become an Agreement State. It was further stated that the CRCPD will continue to work with Wisconsin, other Agreement States, the Organization of Agreement States, and the Commission to maintain coordinated and compatible programs for protection against radiation hazards.

#### NRC staff response:

The comments encouraging approval of the Agreement support the NRC staff's plan to complete the staff assessment documenting that the Commission's criteria for entering into an Agreement are satisfied, and then to request the Commission to approve the Agreement and to place it into effect. These comments are supportive of the Commission's process for approval of an Agreement.

#### **(b) Comments Opposing the Agreement (None received)**

#### **(c) Other**

### Summary of Comments:

**Commenter:****Affiliation:**

Clayton Bradt

Principal Radiophysicist - Radiological Health Unit, New York State  
Department of Labor

#### 1. Sealed Source and Device Review and Registration -

The proposed Agreement reserves the review and registration of sealed sources and devices (SS&D) to the Commission. This would appear to be in violation of the provisions of §274 of the Atomic Energy Act (AEA).

Contrary to the assertion by Commission staff, the term "categories of materials" is not meant to encompass "activities." Section 274 of the AEA is quite explicit about both. In general, the assumption of regulatory authority over "categories of materials" under Chapters 6, 7, & 8 and §161, means the assumption of authority over all activities involving those materials as enumerated in the specified chapters and section, with certain expressly stated exceptions: e.g., the licensing of fuel cycle/utilization facilities, the licensing of the distribution of radioactive devices, and the protection of national security/safeguards information under §161 b and i. Section 274 provides no authorization for the Commission to reserve activities from State authority under an Agreement save for those expressly enumerated. Consequently, the AEA does not permit the Commission to reserve the safety reviews of SS&D from State regulatory authority. In fact, since the AEA does not even mention such reviews, they cannot properly be considered as part of an Agreement.

The proposed Agreement will establish a system of dual regulation of manufacturers and distributors of radioactive devices in Wisconsin, a result which the Agreement State program was intended to avoid. Regardless of who reviews SS&D registrations, the State of Wisconsin must still license the manufacture and distribution of radioactive devices within its borders. And, since it is the license which is legally enforceable, not the SS&D registration certificate, any requirements, restrictions or special procedures needed to ensure the safety of such devices must be included in the conditions of the license in order to be enforced. The effect of such an Agreement unfairly burdens manufacturers/distributors of radioactive devices in the State of Wisconsin, vis-à-vis those located in other States, and could arguably be viewed as an unauthorized restriction of trade by the State of Wisconsin - ironically operating against its own citizens.

### NRC staff response:

This issue was addressed in Commission Paper SECY-95-136 entitled, "Options to Improve and Standardize the Evaluation and Approval of Sealed Sources and Devices Manufactured in Agreement States." By approving Option 2 and with the issuance of Management Directive 5.8 entitled "Proposed 274b Agreements with States," the Commission determined that this activity could be considered as a separate activity which States could choose to address in a Section 274 Standard Agreement. Under this policy, Agreement States have the option whether or not to seek authority to perform sealed source and device evaluations. In our view, this is consistent

with the discretion provided the Commission in the last sentence of Section 274c of the AEA. The Governor of Wisconsin chose not to request this authority in the State's request for an Agreement with the NRC.

## 2. Cooperation with Other Agencies -

The Commission staff state that the proposed Agreement commits Wisconsin "to use its best efforts to cooperate with the NRC and other Agreement States" (emphasis added) in the formulation of standards and regulations "and to assure that Wisconsin's program will continue to be compatible ..." They further state that the proposed Agreement "commits the Commission and Wisconsin to use their best efforts" (emphasis added) to accord reciprocity to each other's licensees and the licensees of other States. This language echoes the bi-lateral commitments first introduced in the Commission's Agreement with the State of New York, in 1962. The intent of this wording, as expressed in then Governor Nelson A. Rockefeller's letter to the Commission, was to better reflect the fact that the relationship between the Commission and the State was to be a cooperative one. In the New York Agreement both the Commission and the State commit to "use their best efforts" to cooperate for the desired result of maintaining compatible regulatory programs. They did not commit themselves to obtaining the desired result, but only to use their "best efforts" to do so. Clearly, for either party to commit to do more than use its best efforts to achieve the mutual goal would place it under the authority of the other - something that a sovereign could never do.

It is curious that the Commission staff use this language in Section II to describe the commitments in the Agreement, when in the text of the Agreement itself this "best efforts" language is replaced by a much more one-sided set of commitments. In Article VI of the proposed Agreement, the Commission agrees that it "will cooperate" to formulate standards and regulations and that it will cooperate to assure the coordination and compatibility of the State and Commission programs. Wisconsin also agrees to cooperate in the formulation of standards and regulations but then agrees that it "will assure" that the State's program will continue to be compatible - a much stronger (and unwise) commitment.

Thus by signing this proposed Agreement, the State of Wisconsin will place itself under the ultimate authority of the Commission. For in practice, the Commission has reserved to itself the sole authority for determining the meaning of "compatibility." By committing itself to obtain the result, Wisconsin commits itself to operate its regulatory program in whatever manner the Commission tells it to. A sovereign cannot commit itself to the achievement of a result, the metric of success for which is controlled by another, and remain sovereign.

The proposed Agreement thus short-changes the residents of the State of Wisconsin, relegating them to a second-class status vis-à-vis those of other States such as New York, as well as violates the provisions and intent of the Atomic Energy Act.

### NRC staff response:

The commenter has expressed a different opinion from the policy approved by the Commission in 1997. The Policy on Adequacy and Compatibility of Agreement State Programs and the accompanying implementation procedures were developed cooperatively with the States, over a period of several years, and are detailed in SECY-97-054 and Management Directive 5.9. The

ultimate interpretation of this policy rests with the Commission. The proposed Wisconsin Agreement is consistent with Commission policy and thus meets the criteria for an Agreement with the Commission. It is also consistent with the Standard Agreement which was previously developed and set out in Management Directive 5.8 "...to establish a system for an orderly transition in the discontinuance of certain regulatory authority by the NRC with assumption thereof by the State through a standard agreement."

In our view, whether or not the phrase "best efforts" is used, the State has agreed to seek continued compatibility. Thus, in our view the difference pointed out by the commenter is not significant. It should be noted that the inconsistency with use of the phrase "best efforts" has been previously recognized in SECY-97-145 (July 11, 1997) which evaluated the language in past agreements against the standard agreement. This evaluation concluded that modifications to the Agreements were not necessary. However, the staff intends to delete the phrase "best efforts" from the Federal Register Notice in the future and make a conforming change to Management Director 5.8.